July 1, 2019

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852


Dear Sir or Madam:

On behalf of AdvaMed, the Advanced Medical Technology Association, we are pleased to submit these comments in response to the Food and Drug Administration’s (FDA’s) request for comments on the List of Patient Preference-Sensitive Priorities.

The Advanced Medical Technology Association (AdvaMed) is the world’s largest trade association representing medical device and diagnostics manufacturers. AdvaMed’s member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed’s member companies range from the smallest to the largest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

AdvaMed has a number of general and specific comments on the patient preference-sensitive information below.

General Comments

Clarification of Patient Preference Information (PPI) Terms
It would be helpful if FDA explained that sponsors may translate the medical terms used in the patient preference list to terms more readily understood by patients (e.g., shortness of breath, dizziness, fluttering vs. the terms permanent or paroxysmal).
Updating PPI List

FDA does not describe how the PPI list will be updated but we understand FDA does have plans to update the PPI list at future points. FDA may want to consider routinely updating the website list of PPI as new patient preference information is successfully used in regulatory decision-making (so long as this does not reveal commercially confidential information). FDA should also issue FR notices (similar to this one) on a routine basis (e.g., annually) requesting input on the patient preference list as this will help drive both review team and sponsor uptake of PPI.

PPI Tools and Training

One of the key challenges to adoption of PPI in regulatory submissions continues to be the lack of trained experts in PPI, the lack of PPI methodology and the resulting high cost. We understand FDA intends to train review teams on use of PPI. Such training should clarify that use of PPI by sponsors is voluntary. We also understand FDA is exploring training with outside groups to demonstrate how to conduct PPI. We strongly support such training efforts as they will facilitate uptake of PPI by FDA, payers, clinicians and sponsors. We would note, payers and clinicians appear to be skeptical about the value of PPI in FDA’s risk-benefit decision-making. Additional FDA-sponsored public meetings that engage payers and clinicians may be of value.

Decisions about whether to pursue PPI as part of a sponsor submission typically reside within companies’ clinical trial staff with input from regulatory or other internal stakeholders. Training and other PPI materials describing PPI methodology or protocols for clinical trial staff, and the value of PPI to facilitating or expediting the review or approval process for regulatory staff would be helpful. We also recommend the development of best practices based on PPI submissions, and as noted above, research and training on the methodology of PPI.

We understand FDA’s PPI staff is also open to a dialogue with companies that are interested in potentially considering PPI with their review division. FDA may want to consider making that openness to dialogue more transparent on FDA’s PPI website. Similarly, we understand FDA has several PPI research projects underway. It would be helpful to highlight these research efforts more prominently on the FDA website (e.g., by putting research initiatives in the sidebar).

Explanation of Priorities List

It would be helpful for FDA to better explain the implications of the PPI priority list for sponsors. For example, it would be helpful for FDA to clarify:

- That PPI studies are voluntary;
- Why these priorities were chosen as opposed to others;
- The value or potential benefit of companies including this kind of information in its regulatory submissions; and
- How use of PPI will facilitate FDA’s review.

It would also be helpful to understand what FDA’s position is on areas that are not on the priority list.
Specific Comments
AdvaMed has one specific recommendation: please add lumbar puncture for Alzheimer’s Disease (AD) diagnosis to the PPI priority list on choice of diagnostic.

Patient Benefit-Risk Tradeoffs Related to:
Choice of diagnostic (such as in vitro device, imaging or lumbar puncture) for diseases such as colon cancer, bladder cancer, prostate cancer, fecal occult blood testing, lupus, rheumatoid arthritis, Alzheimer’s and others.

In response to FDA’s questions for additions to the PPI priority list, please see below.

What is the full impact of the disease or condition and treatment options on patients and/or caregivers?

Answer: Due to the limited availability of current options for an IVD for AD, the costs of alternative approaches to AD diagnosis along with scheduling/traveling logistics (patient and caregiver) need to be weighed against the unknown of a lumbar puncture procedure (patient and caregiver) and the lower cost of the test (patient).

Will patients value the benefits and risks of a technology or treatment differently from healthcare professionals and/or caregivers?

Answer: A healthcare professional may value the benefits and risks of the best test available, while the patient may not understand the differences in the two tests from an analytical perspective and may be more concerned with the cost of the test and/or scheduling/logistics.

Is there a significant public health impact (such as high mortality or morbidity rates and high prevalence rates of the disease, or few treatment options available such as in rare diseases)?

Answer: There are few treatment options and IVDs for Alzheimer’s Disease today which has a significant health impact since it is expected that there will be approximately 13.8 million Americans (Ages 65+) with AD by 2050. This is an increase from 4.7 million Americans in 2010. (https://www.alzheimers.net/resources/alzheimers-statistics/ Accessed June 26, 2019)

In closing, thank you for the opportunity to provide AdvaMed’s comments on the Patient Preference-Sensitive Priorities and related issues. Please don’t hesitate to contact me if I can respond to any questions you may have.

Sincerely,

/s/

Tara Federici
Vice President
Technology and Regulatory Affairs